thereby increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, "*Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*," JAMA, August 22, 2001 at 954.

101. Pharmacologist Dr. Garrett Fitzgerald of the University of Pennsylvania reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that contemporaneous with the Celebrex Defendants' launch it was known that selective COX-2 inhibitors, such as Celebrex, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke. Fitzgerald, G.A., Patrono C., "*The Coxibs, Selective Inhibitors of Cyclooxygenase-2,*" N Engl J Med 2001;345:433-442.

102. Early FDA updates in March and April of 1999 similarly acknowledged this known risk, but noted, based upon Pfizer's representations, that Celebrex "does not affect platelet aggregation (clumping), an important part of the blood clotting process." *See* FDA Updates, *"New Arthritis Drug May Have Fewer Side Effects,"* FDA Consumer March-April 1999.

103. Based on the studies performed on Celebrex, other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, the Celebrex Defendants knew when Celebrex was being developed and tested that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

104. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of Celebrex, the Celebrex Defendants failed to take any action to protect the health and welfare of patients, opting instead to continue promoting the

drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

105. In September 1998, Pharmacia sponsored an allegedly independent Celebrex Long-Term Arthritis Safety Study ("CLASS"). The multicenter, double-blind, parallel group study sought to compare the incidence of clinically significant upper gastrointestinal events between Celebrex 400 mg BID and Ibuprofen 800 mg. (CLASS data is found in NDA 20-998/S-009 submitted to the FDA by Searle on June 12, 2000. CLASS was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D. (FDA Medical Officer) on September 20, 2000.)

106. On September 13, 2000, the Celebrex Defendants released the results of the CLASS study in the *Journal of The American Medical Association (JAMA).* Silverstein, F.E., *et al.*, "*Gastrointestinal Toxicity with Celecoxib vs. Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis: The CLASS Study: A Randomized Controlled Trial,*" 284 JAMA 1247 (2000). Researchers enthusiastically reported a "lower incidence of symptomatic ulcers and ulcer complications combined, as well as other clinically supported toxic effects, compared with NSAIDs at standard doses."

107. Although the Celebrex Defendants touted the CLASS study as the primary evidence to support its theory that Celebrex was safer for consumers who could not tolorate traditional NSAIDs in their gastrointestinal system, the Celebrex Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the results, risks and defects of the CLASS study. Among other things, the Celebrex Defendants failed to release the study's complete twelve month results releasing only the first six months of trials,

reported biased and misleading results, limited conclusions to upper gastrointestinal events despite other known risks factors, and understated known cardiovascular risks.

108. Despite the Celebrex Defendants' favorable CLASS Study conclusions, no other reviewing or administrative body was able to substantiate those findings. The FDA Medical Officer Review of the CLASS data found Celebrex to be no more efficacious than other traditional NSAIDS comparators. *See generally*, FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by Searle on June 12, 2000. According to the FDA's review of the CLASS data: "Celecoxib did not demonstrate any statistical superiority to NSAIDs (pooled) or either comparator (diclofenac and ibuprofen) with regards to the primary safety endpoint of CSUGIE (Clinically Significant Upper Gastrointestinal Adverse Events) at any point in the trial although there were trends that favored celecoxib." (FDA CLASS Review).

109. The FDA Arthritis Advisory Committee similarly found no "clinically meaningful" safety advantage of Celebrex over older NSAIDs. (FDA CDER Arthritis Advisory Committee, February 7th and 8th, 2001, Gaithersburg, Maryland). The CLASS Study failed to demonstrate a superior safety record over ibuprofen or pooled NSAID data. Based on this information, the Committee advised that further studies be done to assess the risk of COX-2 drugs and NSAIDS when taken with aspirin.

110. In a June 2002 editorial, the *British Medical Journal* chastised the Study's "misleading" and "seriously biased" nature; noting that the complete results "clearly contradict[ed] the published conclusions," and warning against the dangers of "overoptimistic," "short-term" data and "post hoc changes to the protocol." Juni, Peter, *et. at., "Are Selective COX 2 Inhibitors Superior To Traditional Non Steroidal Anti-Inflammatory Drugs?"* BMJ 2002;324:1287-1288. Most noticeably, the CLASS study considered only six months of data

despite the fact that researchers at that point had 12 months of data that, when analyzed as a whole, showed no significant difference. Instead of releasing the complete 12-month results from CLASS, Pfizer relied on and published only the first six months of data. JAMA 2000, 48:1455-1460. The results of the completed study revealed the real truth: Celebrex offered no gastrointestinal (GI) benefit. Almost all ulcer-related complications that had occurred during the second half of the CLASS trials were in users of Celebrex. These results clearly contradict the published CLASS conclusions.

111. Editors of the Journal of the American Medical Association (JAMA) and other medical experts were reportedly "flabbergasted" when they realized they had been "duped" by only being provided with the first six months of CLASS data. Okie S., *"Missing data on Celebrex: Full study altered picture of drug,"* Washington Post 2001 Aug 5;Sect A:11. The *Washington Post* reported JAMA editors noting: "When all of the data were considered, most of Celebrex's apparent [GI] safety advantage disappeared."

112. Institutional bias also appeared to play a role in the Study's biased conclusions. According to the *Washington Post*, all sixteen CLASS authors were either employees of Pharmacia or paid consultants of the company. Okie, S., *"Missing data on Celebrex: Full study altered picture of drug,"* Washington Post 2001 Aug 5;Sect A:11. Moreover, at least one author, Dr. M. Michael Wolfe, a gastroenterologist from Boston University, admits he was duped by Pharmacia. In the summer of 2000, *The Journal of the American Medical Association* asked Wolfe to participate in the "six-month" trial. Wolfe found the study, tracking 8,000 patients over a six-month period, persuasive, and penned a favorable review, which helped to drive up Celebrex sales. It was not until early the next year, while serving on the FDA's Arthritis Advisory Committee, that Wolfe learned the study had run for one year, not six months, as the

company had originally led both Wolfe and the *Journal* to believe. *Id.* Here again, when the complete data was considered, most of Celebrex advantages disappeared.

113. The Celebrex Defendants also limited conclusions of the CLASS study to upper gastrointestinal events, despite other known risks factors, and understated known cardiovascular risks. A metastudy by the Cleveland Clinic published in the Journal of the American Medical Association analyzed data from two major studies, including CLASS, funded by the drug companies and two smaller ones—all for cardiovascular risks. Debabrata Mukherjee, *et al.*, "*Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*," 286 JAMA 954 (2001).) The metastudy found that Pharmacia failed to identify and study cardiovascular risks for their products. The annualized heart attack rates for patients taking Vioxx or Celebrex, the researchers found, were "significantly higher" than those in a group taking placebos. "The available data raise a cautionary flag about the risk of cardiovascular events with Cox-2 inhibitors," they concluded.

114. "A total of 36 deaths occurred during the [CLASS] study or during post study follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group . . . . Most deaths were cardiovascular in nature." FDA CLASS Review at 54. The increased number of adverse cardiovascular events in the Celebrex group was not surprising, as they were also revealed in the original New Drug Application (NDA) submitted for Celebrex. "In the original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as compared to placebo treated patients. In the long term trial (Trial 024) that was included in the NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any dose was cardiovascular." FDA CLASS Review at 78.

115. Public Citizen, a public watchdog organization, also reviewed the CLASS data in its entirety. A complete review reveals the combined anginal adverse events was 1.4% in the Celebrex group versus 1.0% in either NSAID group. Specifically, the rate of heart attack in the Celebrex was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

116. Eric Topol of the Cleveland Clinic reached a similar conclusion, noting that the CLASS trial MI rate was 1.6% in the Celebrex group (at a dosage of 400 mg twice a day) and 1.2% in the ibuprofen group for the 1739 patients taking low-dose aspirin. Topol noted that this numerical excess, albeit not statistically signification, was also found in the 6229 patients not taking aspirin in the trial. Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events – House of Coxibs,"* JAMA 293:366. Based on this data, Topol and his colleagues concluded: "It is mandatory to conduct a trial specifically assessing cardiovascular morbidity." *Id.* Unfortunately, no such trials were ever initiated, delaying the official warnings of Celebrex and jeopardizing countless lives in the process.

117. The CLASS data proves that Pfizer knew that its first generation COX-2 inhibitor, Celebrex, caused a disproportionately and statistically significant high number of adverse cardiovascular events before it was introduced to the market in January 1999. According to Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the cardiovascular risks of COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this placebo-controlled trial of Celebrex.

118. In early 2000, the National Cancer Institute (NCI), in collaboration with Searle and Pfizer, initiated the Adenoma Prevention with Celecoxib (APC) trial, a randomized, double-blind, placebo-controlled study to discover the efficacy of Celebrex in preventing the growth of pre-cancerous colon polyps. N.ENG. J. MED. 352;11 at 1072. The trial involved 2026 patients

across the country with randomization to one of three groups: (1) placebo; (2) 200 mg Celebrex twice daily; and (3) 400 mg Celebrex twice daily. The patients, each of whom had an adenomatous polyp removed before enrollment, were followed up for a mean of 33 months while taking the study drug, with the primary objective of limiting the development of colorectal cancer.

119. On December 17, 2004, the National Cancer Institute suspended the use of Celebrex for all participants in the APC trial due to "significant excess of cardiovascular death, myocardial infarction (MI) and stroke." Eric J. Topol, "*Arthritis Medicines and Cardiovascular Events – House of Coxibs,*" JAMA 293:366. Analysis by an independent Data Safety Monitoring Board (DSMB) showed a two to three fold increased risk of major fatal and non-fatal cardiovascular events for participants taking the drug compared to those on a placebo with a secondary dose-response effect.

120. The absolute excess of major cardiovascular events of 13/1000 patients at the 800 mg dose (400 mg 2x day) was strikingly similar to the results of trials with rofecoxib and valdecoxib, both selective NSAID COX-2 inhibitors removed for the market for their significant cardiovascular risks. Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events – House of Coxibs,"* JAMA 293:366.

121. The FDA reported similar results, noting:

> In the National Cancer Institute's Adenoma Prevention with Celecoxib (APC) trial in patients at risk for recurrent colon polyps, a 2-3 fold increased risk of serious adverse CV events was seen for Celebrex compared to placebo after a mean duration of treatment of 33 months. There appeared to be a dose response relationship, with a hazard ratio of 2.5 for Celebrex 200 mg twice daily and 3.4 Celebrex 400 mg twice daily for the composite endpoint of death from CV causes, myocardial infarction (MI), or stroke.

April 7, 2005 FDA Alert: www.fda.gov/cder/drug/infopage/Celebrex/Celebrex-hcp.htm.

122. The dosage noted in the study is itself important for two reasons: first, there appears to be an association between dosage and the increase in adverse cardiovascular events; second, most patients increase dosage. Pfizer knew patients were increasing their dosages as noted in the CLASS Study: "Interestingly ... up to 70% of patients increased their dose for celecoxib." FDA CLASS Review at 74. Thus, Pfizer was aware of "dosage creep."

123. Several other Celebrex trials also gave the Celebrex Defendants insight into the cardiovascular risks presented by Celebrex. The Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, stroke, heart failure, angina, or need for CV procedure) as 3.6% with Celebrex as compared to 2.7% for placebo.

124. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected "the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold increase in CV risk in those people taking celecoxib. (p=0.03)." *Public Citizen*, January 26, 2005, Dr. Sidney M. Wolfe. According to Dr. Sidney Wolfe, "The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV deaths in people using celecoxib compared to those using placebo." Id.

125. Pfizer also had access to other data, which indicated a cardiovascular risk with its drugs. Specifically, Pfizer had knowledge of the two studies conducted by Merck related to its Cox-2 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROVe).

126. In 2000, The FDA Medical Officer Review of CLASS specifically noted the VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS Review at 78.

127. According to VIGOR, Vioxx patients experienced 20% more serious clinical adverse events (statistically significant); they experienced 4.6 times more hypertension events serious enough to warrant discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice the risk of naproxen and the results were considered statistically significant.

128. The VIGOR study comprised the most definitive scientific evidence ever obtained about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of medical research. It was a safety study with endpoints set in advance. As Merck stated many times, it was designed to provide definite proof of safety, convincing enough to silence the most skeptical critics. In medical terms, the VIGOR results raised the question of whether selective inhibition of COX-2 was a monumental mistake from the start. While the NSAID risks to the GI system were real and sometimes fatal, they were dwarfed by the cardiovascular risks of the arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including the Celebrex Defendants, were aware of these results.

129. Anxious to put safety questions surrounding Vioxx to rest, Merck designed another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of the APPROVe data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and

"doubled the risk of MI (myocardial infarction a/k/a heart attack)[1]. *Public Citizen*, January 24, 2005, at 15. Despite the available Celebrex data and other information related to Vioxx, Pfizer never paused to reevaluate the Celebrex data and studies.

130. The scientific data available during and after Celebrex's approval process made clear to the Celebrex Defendants that their formulation of Celebrex would cause a higher risk of blood clots, stroke and/or myocardial infarctions among Celebrex consumers, alerting them to the need to do additional and adequate safety studies.

131. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining The Celebrex Defendants' failure to have conducted the necessary trials before marketing to humans, "it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events."

132. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

133. Based upon readily available scientific data, the Celebrex Defendants knew, or should have known, that their pre-approval testing of Celebrex did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take Celebrex. Therefore, the Celebrex Defendants' testing and studies were grossly inadequate.

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[1] Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVe trial did not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant increase in risk of heart attack was evident in as little as 4 months time.

134. Had the Celebrex Defendants done adequate testing prior to approval and market launch, rather than the extremely short duration studies done on the small size patient base that was actually done, the Celebrex Defendants' scientific data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of Celebrex consumers. Adequate testing would have shown that Celebrex possessed serious side effects. The Celebrex Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects.

135. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but the Celebrex Defendants intentionally suppressed this information in order to gain significant profits from continued Celebrex sales.

136. The Celebrex Defendants' failure to conduct adequate testing and/or additional testing prior to market launch was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

137. As is detailed herein, at the time the Celebrex Defendants manufactured, advertised, and distributed Celebrex to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers would not purchase Celebrex, but instead would purchase other cheaper and safer NSAIDs. The Celebrex Defendants' conduct was therefore wanton and willful, and displayed a

conscious disregard for Virginia E. Buchanan's safety, in particular, and the public in general, entitling her to exemplary damages.

138. The Celebrex Defendants widely and successfully marketed Celebrex throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of Celebrex in order to induce a widespread use and consumption. The Celebrex Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff's prescribing physicians.

139. Despite knowledge of the dangers presented by Celebrex, the Celebrex Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Celebrex and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in Celebrex. The Celebrex Defendants and their officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of Celebrex, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. The Celebrex Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

140. Such an ineffective and unreasonably dangerous drug could only be widely prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the Celebrex Defendants' marketing campaign was fraudulent and misleading. But for fraudulent and misleading advertising, consumers, including the Plaintiff, would not have purchased Celebrex, a more costly prescriptive drug, ineffective for its intended purposes.

141. Defendant's marketing was so fraudulent that the FDA issued three Warning Letters to the Celebrex Defendants in October 1999, April 2000, and November 2000, all finding that Defendants were unlawfully making false or misleading statements concerning the safety and/or efficacy of Celebrex. The November letter cited two direct-to-consumer television advertisements that overstated the efficacy of Celebrex. The FDA ordered that Searle immediately cease distribution of the misleading ads.

142. On February 2001, the FDA issued a Warning Letter to Pharmacia stating that promotional activities from marketing Celebrex were unlawful because they were "false, lacking in fair balance, or otherwise misleading." The FDA found that Celebrex had been promoted for unapproved uses, in unapproved dosing regiments, and that the marketers had made unsupportable claims that Celebrex was safer and more effective than other NSAIDs.

143. In August 2001, it was revealed that Pharmacia had misrepresented the results of a post-marketing clinical study of Celebrex when submitting it for publication. Pharmacia selectively omitted portions of the data relating to adverse effects. The *Washington Post* reported on August 5, 2001 that, "the study had lasted a year, not six months as . . .thought. Almost all of the ulcer complications that occurred during the second half of the study were in Celebrex users. When all of the data were considered, most of Celebrex's apparent safety advantage [as compared to traditional NSAIDs] disappeared."

144. On January 10, 2005 the FDA again issued Pfizer a written reprimand for its promotional activities. The reprimand reads: "These five promotional pieces [3 Celebrex and 2 Bextra] variously: omit material facts … and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims." Amid continued frustration with Pfizer's continually misleading marketing strategy and ever surmounting evidence of cardiovascular

dangers, the FDA Advisory Panel voted overwhelmingly that the company should never again advertise the drug [Celebrex]."

145. At all times relevant herein, the Celebrex Defendants engaged in a marketing campaign with the intent that consumers would perceive Celebrex as a safer and better drug than its other NSAIDs and, therefore, purchase Celebrex.

146. In an elaborate and sophisticated manner, the Celebrex Defendants aggressively marketed Celebrex directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payors, medical care organizations, and large institutional buyers (*e.g.*, hospitals) to include Celebrex on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from the Celebrex Defendants' successful advertising and marketing blitz, third party payors were compelled to add Celebrex to their formularies. The Celebrex Defendants' marketing campaign specifically targeted third party payors, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of Celebrex.

147. The Celebrex Defendants represented that Celebrex was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). The Celebrex Defendants promoted Celebrex as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

148. Yet, Celebrex possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable

angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as strokes. In addition, Celebrex, which is significantly more expensive than traditional NSAIDs[2], was actually no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Yet, the Celebrex Defendants chose not to warn about these risks and dangers.

149. The Celebrex Defendants knew of these risks before FDA approved Celebrex for sale, but Defendants ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing, and sale of Celebrex. The Celebrex Defendants' omission, suppression, and concealment of this important information enabled Celebrex to be sold to, and purchased, or paid for by consumers at a grossly inflated price.

150. Consequently, Celebrex captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of Celebrex exceeded $2 billion, despite the significantly higher cost of Celebrex as compared to other pain relievers in the same family of drugs.

151. Because the Celebrex Defendants engaged in a promotional and marketing campaign that featured an advertising blitz directly targeted to consumers, and that touted Celebrex as a safer drug than other drugs in its class, while uniformly failing to disclose the health risks of Celebrex, Defendants were able to justify pricing Celebrex significantly higher than the cost of generic aspirin. In reality, that price inflation was not justified. Had the Celebrex Defendants disclosed the truth about Celebrex, Defendants would not and could not

[2] The cost of Celebrex is at least $3-$6 per day, while an over-the-counter NSAID can cost $.50 or less per day.

have reaped the billions of dollars in Celebrex sales that were achieved as a direct result of the concealment, omission, suppression, and obfuscation of the truth.

152. The Celebrex Defendants intentionally, deliberately, knowingly, and actively concealed, omitted, suppressed, and obfuscated important and material information regarding the risks, dangers, defects, and disadvantages of Celebrex from Plaintiff, the public, the medical community, and regulators. This concealment and omission was deliberate, knowing, active, and was intended to induce and maximize sales and purchases of Celebrex, and prevented Plaintiff from obtaining all the material information that would be important to [his/her] decision as a reasonable person to purchase, and/or use Celebrex.

153. The Celebrex Defendants' systematic, active, knowing, deliberate, and uniform concealment, omissions, suppression, and conduct caused Plaintiff to purchase, and/or use Celebrex; and caused Plaintiff's losses and damages as asserted herein.

154. Had the Celebrex Defendants done adequate testing prior to approval and "market launch," Defendants' scientific data would have revealed significant increases in stroke and myocardial infarction amongst the intended population of Celebrex consumers. Adequate testing would have shown that Celebrex possessed serious side effects. The Celebrex Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects.

155. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but the Celebrex Defendants intentionally suppressed this information in order for them to gain significant profits from continued Celebrex sales.

156. The Celebrex Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch," and active concealment and failure to warn the medical community and general public of the known cardiovascular risks of Celebrex was particularly negligent, reckless and/or malicious given the drug's known target market. The Celebrex Defendants were well aware that most patients taking Celebrex are elderly and have higher risk of developing cardiovascular risks to begin with. Nearly half of the patients with arthritis have coexisting cardiovascular disease, and most patients, as discovered in the CLASS study, were prone to higher dosing.

157. The Celebrex Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

158. At the time the Celebrex Defendants manufactured, advertised, and distributed Celebrex to consumers including Plaintiff, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarction because Defendants knew that if such increased risks were disclosed, consumers would not purchase Celebrex, but instead would purchase other cheaper and safer NSAID drugs.

159. At the time Plaintiff was given Celebrex, she was not warned or aware of the serious and debilitating health effects of taking Celebrex because no warnings were communicated to her or to [his/her] physician by Defendants.

160. The Celebrex Defendants acted with conscious and wanton disregard for the health and safety of Virginia E. Buchanan, in particular, and the public in general. Therefore, Plaintiff is entitled to an award of additional damages for the sake of example and for the

purpose of punishing Defendants for the conduct, in an amount sufficiently large to be an example to others and to deter Defendants and others from engaging in similar conduct in the future. The above-described wrongful conduct was done with knowledge, authorization and ratification of the officers, directors, managing agents and/or employees of Defendants.

COUNT I

NEGLIGENCE

161. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

162. Defendants owed all individuals purchasing Vioxx and Celebrex in the ordinary stream of commerce, including Plaintiff, the duty of reasonable care and safety. Defendants' duties included but were not limited to taking all reasonable and necessary care to 1) properly design, test and manufacture Vioxx and Celebrex; 2) safeguard individuals from hazards of Vioxx or Celebrex which they knew or should have known about; 3) discover latent defects or hazards of the products; 4) ensure the drugs were safe and effective; 4) inform the public and those prescribing Vioxx and Celebrex of the potential hazards of the drugs, including the risk of cardiovascular accidents.

163. Defendants breached said duties in that Vioxx and Celebrex were defective, unreasonably dangerous and hazardous in one or more of the following ways:

(a) The drugs failed to include adequate warnings that would alert consumers and physicians to the potential risks and serious side effects of the drugs;

(b) Defendants failed to adequately and properly test the drugs before placing the drugs on the market;

(c) Defendants failed to conduct sufficient testing on the drugs, which, if properly performed, would have showed that the drugs had serious side effects including, but not limited to, adverse cardiac and cardiovascular events;

(d) Defendants failed to adequately warn Plaintiff that the testing that was done revealed an increased risk of adverse cardiac and cardiovascular events related to this class of drugs;

(e) Defendants failed to adequately warn Plaintiff that the use of the drugs carried a risk of temporary or permanent disability or death due to adverse cardiovascular events and other serious side effects;

(f) Defendants failed to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the drugs;

(g) Defendants encouraged misuse and overuse of the drugs while downplaying the side effects to doctors and the public and by overstating the benefits of Vioxx and Celebrex in order to make a profit from their sale.

164. Defendants knew or should have known that the drugs caused unreasonably dangerous risks and serious side effects of which the Plaintiff would not be aware. Defendants nevertheless advertised, marketed, sold and distributed the drugs knowing that there were safer methods for treatment.

165. Defendants knew or should have known that consumers, like Plaintiff, would suffer injury as a result of their failure to exercise ordinary care as described above.

166. As a direct and proximate result of Plaintiff's reliance on the incomplete and inaccurate information communicated by Defendants, and her assumption that the non-disclosed

facts about the risks associated with the use of Vioxx and Celebrex did not exist, Plaintiff sustained serious and permanent injuries including, but not limited to a stroke and other physical injuries; disability, mental anguish, severe pain and suffering; loss of capacity for the enjoyment of life; and expenses of medication, physicians, hospitals, and medical and nursing care and treatment.

167. At all times relevant hereto, Defendants actually knew of the defective nature of the products as herein set forth and continued to design, manufacture, market and sell the products so as to maximize sales and profits at the expense of public health and safety. Defendants' conduct exhibits a wanton or reckless disregard for human life and public safety and such an entire want of care as to establish that their actions were a result of fraud, evil motive, actual malice, and the conscious and deliberate disregard of foreseeable harm to consumers, including Plaintiff. Therefore, Plaintiff is entitled to punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants Merck, Pfizer, Pharmacia, Monsanto, and Searle and prays for relief as follows:

A. For $10,000,000 in compensatory damages;

B. For $20,000,000 in punitive damages;

C. For compensation for medical, incidental and hospital expenses;

D. For interest and costs;

E. For such other extraordinary, declaratory and/or injunctive relief as permitted by law as necessary to assure that Plaintiff has an effective remedy; and

F. For such further relief as this Court deems necessary, just and proper.

COUNT II

(Strict Products Liability – Failure To Warn)

168. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

169. Vioxx and Celebrex were defective and unreasonably dangerous when they left the possession of Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with the drugs including, but not limited to, adverse cardiac events, cerebrovascular accidents and other serious and life-threatening side effects.

170. Plaintiff used the drugs for their intended purposes in a manner reasonably anticipated without knowledge of their defective and dangerous characteristics.

171. Plaintiff was an ordinary consumer and user of the products sold, distributed, supplied, manufactured, designed, developed, marketed and/or promoted by Defendants and, therefore, it was foreseeable that Plaintiff would purchase and use the products as indicated herein.

172. The warnings that were given by Defendants were not accurate or clear, but were inadequate as to the frequency, character, severity, and spectrum of injuries caused by Vioxx and Celebrex.

173. Defendants had a continuing duty to warn Plaintiff of the dangers associated with the drugs.

174. As a direct and proximate result of Plaintiff's reliance on the incomplete and inaccurate information communicated by Defendants, and her assumption that the non-disclosed facts about the risks associated with the use of Vioxx and Celebrex did not exist, Plaintiff

sustained serious and permanent injuries including, but not limited to a stroke and other physical injuries; disability, mental anguish, severe pain and suffering; loss of capacity for the enjoyment of life; and expenses of medication, physicians, hospitals, and medical and nursing care and treatment.

175. At all times relevant hereto, Defendants actually knew of the defective nature of the products as herein set forth and continued to design, manufacture, market and sell the products so as to maximize sales and profits at the expense of public health and safety. Defendants' conduct exhibits a wanton or reckless disregard for human life and such an entire want of care as to establish that their actions were a result of fraud, evil motive, actual malice, and the conscious and deliberate disregard of foreseeable harm to Plaintiff. Therefore, Plaintiff is entitled to punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants Merck, Pfizer, Pharmacia, Monsanto, and Searle and prays for relief as follows:

A. For $10,000,000 in compensatory damages;

B. For $20,000,000 in punitive damages;

C. For compensation for medical, incidental and hospital expenses;

D. For interest and costs;

E. For such other extraordinary, declaratory and/or injunctive relief as permitted by law as necessary to assure that Plaintiff has an effective remedy; and

F. For such further relief as this Court deems necessary, just and proper.

COUNT III

(Strict Product Liability Design Defect)

185. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

186. At all times material hereto, Defendants engaged in the business of selling, distributing, supplying, marketing, manufacturing, developing, designing and promoting the drugs Vioxx and Celebrex in the course of Defendants' respective businesses.

187. Defendants sold the products Vioxx and Celebrex, which were ingested by Plaintiff, as described in this Complaint.

188. Vioxx and Celebrex, as manufactured by Defendants, were defective at the time they were sold by the defendants and/or left Defendants' control.

189. The Vioxx and Celebrex ingested by Plaintiff, were expected to and did reach the user, Plaintiff without substantial change from how they were sold.

190. Plaintiff was a person who would be reasonably expected to consume the products and who did consume the products in a manner reasonable anticipated by Defendants.

191. Vioxx and Celebrex when sold, distributed, supplied, manufactured, designed, developed, marketed and promoted by Defendants were unreasonably dangerous when put to a reasonably anticipated use as said products cause or contribute to serious adverse cardiac and cerebrovascular events including, but not limited to heart attack, cerebrovascular accident and hypertension.

192. Vioxx and Celebrex, when sold, distributed, supplied, manufactured, designed, developed, marketed and promoted by Defendants were defective when they left the hands of the

Defendants in that said products were more dangerous than the ordinary user or consumer would expect.

193. At all times material hereto, Vioxx and Celebrex were sold, distributed, supplied, manufactured, designed, developed, marketed and/or promoted by Defendants in a defective and unreasonably dangerous condition in ways which include, but are not limited to, one or more of the following particulars:

(a) When placed in the stream of commerce, the drugs contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Plaintiff to risks which exceeded the benefits of the drugs;

(b) When placed in the stream of commerce, the drugs were defective in design and formulation, making their use more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with other treatments for pain relief that were available;

(c) The drugs were insufficiently tested;

(d) The drugs caused harmful side effects which outweighed any potential utility;

(e) The drugs were not accompanied by adequate instructions and/or warnings to fully apprise the consumers, including Plaintiff, of the full nature or extent of the risks and side effects associated with their use.

(f) As a direct and proximate result of Plaintiff's reliance on the incomplete and inaccurate information communicated by Defendants, and her assumption that the non-disclosed facts about the risks associated with the use of Vioxx and Celebrex did not exist, Plaintiff sustained serious and permanent injuries including, but not limited to a stroke and other physical injuries; disability, mental anguish, severe pain and suffering; loss of capacity for the enjoyment of life; and expenses of medication, physicians, hospitals, and medical and nursing care and treatment.

194. At all times relevant hereto, Defendants actually knew of the defective nature of the products as herein set forth and continued to design, manufacture, market and sell the products so as to maximize sales and profits at the expense of public health and safety. Defendants' conduct exhibits a wanton or reckless disregard for human life and such an entire want of care as to establish that their actions were a result of fraud, evil motive, actual malice, and the conscious and deliberate disregard of foreseeable harm to the Plaintiff. Therefore, Plaintiff is entitled to punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants Merck, Pfizer, Pharmacia, Monsanto, and Searle and prays for relief as follows:

A. For $10,000,000 in compensatory damages;

B. For $20,000,000 in punitive damages;

C. For compensation for medical, incidental and hospital expenses;

D. For interest and costs;

E. For such other extraordinary, declaratory and/or injunctive relief as permitted by law as necessary to assure that Plaintiff has an effective remedy; and

F. For such further relief as this Court deems necessary, just and proper.

COUNT IV

(Fraud)

196. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

197. Defendants concealed facts regarding Vioxx and Celebrex from the consuming public, including Plaintiff, which they had a duty to disclose.

198. The facts concealed and not disclosed include, but are not limited to, those set forth in the general allegations of this Complaint.

199. Each of the facts concealed and not disclosed was material.

200. Defendants concealed material facts to the consuming public with the intent that the consuming public, like Plaintiff, would take a course of action that it would otherwise not have taken if it had been informed of the actual facts known to Defendants, including, but not limited to, the totality of the risks associated with the ingestion of Vioxx and/or Celebrex.

201. Plaintiff and her prescribing physician's reliance upon Defendants' misrepresentations was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Vioxx and/or Celebrex. Defendants aggressively marketed the use of Vioxx and Celebrex and concomitantly downplayed the risks, inducing her physician to prescribe the drugs and inducing Plaintiff to use the drugs.

202. Plaintiff took such action relying on the assumption that the undisclosed facts did not exist and/or were different than they actually were.

203. As a direct and proximate result of Plaintiff's reliance on the incomplete and inaccurate information communicated by Defendants, and her assumption that the non-disclosed facts about the risks associated with the use of Vioxx and Celebrex did not exist, Plaintiff sustained serious and permanent injuries including, but not limited to a stroke and other physical injuries; disability, mental anguish, severe pain and suffering; loss of capacity for the enjoyment of life; and expenses of medication, physicians, hospitals, and medical and nursing care and treatment.

204. At all times relevant hereto, Defendants actually knew of the defective nature of the products as herein set forth and continued to design, manufacture, market and sell the products so as to maximize sales and profits at the expense of public health and safety. Defendants' conduct exhibits a wanton or reckless disregard for human life and such an entire want of care as to establish that their actions were a result of fraud, evil motive, actual malice, and the conscious and deliberate disregard of foreseeable harm to Plaintiff. Therefore, Plaintiff is entitled to punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants Merck, Pfizer, Pharmacia, Monsanto, and Searle and prays for relief as follows:

A. For $10,000,000 in compensatory damages;

B. For $20,000,000 in punitive damages;

C. For compensation for medical, incidental and hospital expenses;

D. For interest and costs;

E. For such other extraordinary, declaratory and/or injunctive relief as permitted by law as necessary to assure that Plaintiff has an effective remedy; and

F. For such further relief as this Court deems necessary, just and proper.

COUNT V

(Breach of Express Warranties)

205. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

206. Vioxx and Celebrex, which were designed, tested, manufactured, distributed, promoted and sold by Defendants, were expected to, and did, reach Plaintiff, without a substantial change in their condition.

207. Defendants, through, but not limited to, their labeling, package inserts, submissions to the FDA, advertising and promotional materials, expressly warranted that Vioxx and Celebrex were safe for the use for which they were intended, namely as a pain relief medication.

208. Defendants breached said express warranties in that Vioxx and Celebrex were unsafe in light of the risk of life-threatening side effects associated with their use, including, but not limited to, adverse cardiac events and cerebrovascular accidents.

209. Plaintiff relied to her detriment on the express warranties of Defendants.

210. As a direct and proximate result of Plaintiff's reliance on the incomplete and inaccurate information communicated by Defendants, and her assumption that the non-disclosed facts about the risks associated with the use of Vioxx and Celebrex did not exist, Plaintiff sustained serious and permanent injuries including, but not limited to a stroke and other physical

injuries; disability, mental anguish, severe pain and suffering; loss of capacity for the enjoyment of life; and expenses of medication, physicians, hospitals, and medical and nursing care and treatment.

WHEREFORE, Plaintiff demands judgment against Defendants Merck, Pfizer, Pharmacia, Monsanto, and Searle and prays for relief as follows:

A. For $10,000,000 in compensatory damages;

B. For compensation for medical, incidental and hospital expenses;

C. For interest and costs;

D. For such other extraordinary, declaratory and/or injunctive relief as permitted by law as necessary to assure that Plaintiff has an effective remedy; and

E. For such further relief as this Court deems necessary, just and proper.

COUNT VI

(Breach of Implied Warranties)

211. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

212. Vioxx and Celebrex, which were designed, tested, manufactured, distributed, promoted and sold by Defendants, were expected to, and did, reach Plaintiff, without a substantial change in their condition.

213. Defendants, through, but not limited to, their labeling, package inserts, submissions to the FDA, advertising and promotional materials, impliedly warranted that Vioxx and Celebrex were of merchantable quality and safe for the use for which they were intended, namely as pain relief medications.

214. Defendants breached said implied warranties in that Vioxx and Celebrex were unsafe in light of the risk of life-threatening side effects associated with their use, including, but not limited to, adverse cardiac events and cerebrovascular accidents.

215. Plaintiff reasonably relied, to her detriment, on the implied warranties of Defendants.

216. As a direct and proximate result of Plaintiff's reliance on the incomplete and inaccurate information communicated by Defendants, and her assumption that the non-disclosed facts about the risks associated with the use of Vioxx and Celebrex did not exist, Plaintiff sustained serious and permanent injuries including, but not limited to a stroke and other physical injuries; disability, mental anguish, severe pain and suffering; loss of capacity for the enjoyment of life; and expenses of medication, physicians, hospitals, and medical and nursing care and treatment.

WHEREFORE, Plaintiff demands judgment against Defendants Merck, Pfizer, Pharmacia, Monsanto, and Searle and prays for relief as follows:

A. For $10,000,000 in compensatory damages;

B. For compensation for medical, incidental and hospital expenses;

C. For interest and costs;

D. For such other extraordinary, declaratory and/or injunctive relief as permitted by law as necessary to assure that Plaintiff has an effective remedy; and

E. For such further relief as this Court deems necessary, just and proper.

COUNT VII

(Deceptive Trade Practices)

217. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

218. Defendants, by misrepresenting the safety of Vioxx and Celebrex and concealing their risks with the intent that consumers like Plaintiff would rely upon such concealment, violated MD. Code Ann., Com. Law §§ 13-101 et seq. (1999).

219. In violation of the Maryland Consumer Protection Act, Defendants withheld the risk of adverse cerebrovascular and cardiac events associated with their products, which was known to Defendants.

220. As a direct and proximate result of Plaintiff's reliance on the incomplete and inaccurate information communicated by Defendants, and her assumption that the non-disclosed facts about the risks associated with the use of Vioxx and Celebrex did not exist, Plaintiff sustained serious and permanent injuries including, but not limited to a stroke and other physical injuries; disability, mental anguish, severe pain and suffering; loss of capacity for the enjoyment of life; and expenses of medication, physicians, hospitals, and medical and nursing care and treatment.

221. At all times relevant hereto, Defendants actually knew of the defective nature of the products as herein set forth and continued to design, manufacture, market and sell the products so as to maximize sales and profits at the expense of public health and safety. Defendants' conduct exhibits a wanton or reckless disregard for human life and such an entire want of care as to establish that their actions were a result of fraud, evil motive, actual malice,

and the conscious and deliberate disregard of foreseeable harm to Plaintiff. Therefore, Plaintiff is entitled to punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants Merck, Pfizer, Pharmacia, Monsanto, and Searle and prays for relief as follows:

A. For $10,000,000 in compensatory damages;

B. For $20,000,000 in punitive damages;

C. For reasonable attorney's fees

D. For compensation for medical, incidental and hospital expenses;

E. For interest and costs;

F. For such other extraordinary, declaratory and/or injunctive relief as permitted by law as necessary to assure that Plaintiff and has an effective remedy; and

G. For such further relief as this Court deems necessary, just and proper.

COUNT VIII

(Loss of Consortium)

222. Plaintiffs Virginia E. Buchanan and Sherman T. Buchanan, Sr. hereby repeat and incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

223. Virginia E. Buchanan and Sherman T. Buchanan, Sr. were married on or about August 28, 1965. They were husband and wife at the time of the occurrences referred to in this Complaint. They continue to be husband and wife.

224. The conduct of the Defendants, set forth in paragraphs 1 through 221 above, caused injury to the marital relationship of Plaintiffs Virginia E. Buchanan and Sherman T.

Buchanan, Sr., including loss of society, affection, assistance, companionship and sexual relations.

WHEREFORE, Plaintiffs Virginia E. Buchanan and Sherman T. Buchanan, Sr. pray for relief as follows:

A. For $10,000,000 in compensatory damages;

B. For costs and interest; and

C. For such further relief as this Court deems necessary, just and proper.

Patricia Kasputys
Peter G. Angelos (Fed Bar #01645)
M. Albert Figinski (Fed Bar #02291)
H. Russell Smouse (Fed Bar #01637)
Patricia J. Kasputys (Fed Bar #03775)

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Telephone: 410-649-2000
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Attorneys for Plaintiff

REQUEST FOR JURY TRIAL

Plaintiffs, by undersigned counsel, hereby request a jury trial on all counts in this action.

Patricia Kasputys
Patricia J. Kasputys